4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA-2015-F-4317]

Center for Science in the Public Interest, Natural Resources Defense Council, Center for Food Safety, Consumers Union, Improving Kids' Environment, Center for Environmental Health, Environmental Working Group, Environmental Defense Fund, and James Huff; Filing of Food Additive Petition; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the notice of filing that appeared in the Federal Register of January 4, 2016. In the notice, FDA requested comments on a filed food additive petition (FAP 5A4810), submitted by the Center for Science in the Public Interest, Natural Resources Defense Council, Center for Food Safety, Consumers Union, Improving Kids' Environment, Center for Environmental Health, Environmental Working Group, Environmental Defense Fund, and James Huff, proposing that the food additive regulations be amended to no longer authorize the use of seven listed synthetic flavoring food additives and to establish zero tolerances for the additives. We are taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: We are extending the comment period on the notice of filing of a food additive petition published on January 4, 2016 (81 FR 42). Submit either electronic or written comments by May 3, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on http://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2015-F-4317 for "Center for Science in the Public Interest, Natural Resources Defense Council, Center for Food Safety, Consumers Union, Improving Kids' Environment, Center for Environmental Health, Environmental Working Group, Environmental Defense Fund, and James Huff, Filing of Food Additive Petition." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of

Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Judith Kidwell, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-1071.

SUPPLEMENTARY INFORMATION: In the Federal Register of January 4, 2016 (81 FR 42), we published a notice of filing of a food additive petition (FAP 5A4810) submitted by the Center for Science in the Public Interest, Natural Resources Defense Council, Center for Food Safety, Consumers Union, Improving Kids' Environment, Center for Environmental Health, Environmental Working Group, Environmental Defense Fund, and James Huff, c/o Mr. Thomas Neltner, 1875 Connecticut Ave., N.W., Suite 600, Washington, D.C. 20009. The notice also invited comments on the petition. The petition proposes to amend 21 CFR 172.515, Synthetic

flavoring substances and adjuvants, to no longer provide for the use of seven listed synthetic flavoring food additives and to establish zero tolerances for these additives. Specifically, the petitioners contend that new data establish that these substances are carcinogenic and are, therefore, not safe for use in food pursuant to the Delaney Clause (section 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(c)(3)(A))), which provides that no food additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal.

The seven food additives which are the subject of the petition are:

- Benzophenone (also known as diphenylketone) (CAS No. 119-61-9);
- Ethyl acrylate (CAS No. 140-88-5);
- Eugenyl methyl ether (also known as 4-allylveratrole or methyl eugenol) (CAS No. 93-15-2);
- Myrcene (also known as 7-methyl-3-methylene-1,6-octadiene) (CAS No. 123-35-3);
- Pulegone (also known as p-menth-4(8)-en-3-one) (CAS No. 89-82-7);
- Pyridine (CAS No. 110-86-1); and
- Styrene (CAS No. 100-42-5).

We have received a request for a 60-day extension of the comment period for the petition. The request conveyed concern that the current 60-day comment period does not allow sufficient time to collect and provide data and information and develop a meaningful and thoughtful response to the assertions set forth in the petition.

We have considered the request and are extending the comment period for the petition for an additional 60 days, until May 3, 2016. We believe that a 60-day extension allows adequate

time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

Dated: February 18, 2016.

Dennis M. Keefe,

Director,
Office of Food Additive Safety,
Center for Food Safety and Applied Nutrition.
[FR Doc. 2016-03708 Filed: 2/22/2016 8:45 am; Publication Date: 2/23/2016]